



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 31, 1999

Alan H. Kaplan
Kleinfeld, Kaplan & Becker
1140 Nineteenth St. NW
Washington, DC 20036-6601

FILE COPY

Dear Mr. Kaplan:

Your petition requesting the Food and Drug Administration to adopt a policy under which the 180-day exclusivity period must expire before approval of a subsequent abbreviated new drug application, was received by this office on 03/30/99. It was assigned docket number 99 P-0792/CP 1 and it was filed on 03/31/99. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie C. Butler
Dockets Management Branch

99P-0792

ACK ~~CP~~ 1